DRAFT - March 18, 1986

PRIVILEGED AND CONFIDENTIAL
ATTORNEYS' WORK PRODUCT

QUESTIONS AND ANSWERS CONCERNING INGREDIENTS

1. Why are ingredients used?

ANSWER: Some ingredients aid in processing tobacco in the initial stages of cigarette manufacture; these ingredients increase the efficiency and yield of processing operations but remain in the final cigarette, if at all, only in trace amounts. Other ingredients are used as casing materials or humectants. Casing materials help to smooth the taste of cigarettes, while humectants keep the tobacco in cigarettes moist, to assure a more even rate of burning. Finally, many of the ingredients are used to give individual brands of cigarettes their distinctive flavor and aroma.

2. How long have ingredients been used in cigarettes?

ANSWER: Ingredients have always been used in cigarettes. Most of the principal processing aids, casing materials, and humectants, for example, have not changed for decades. Many of the major flavoring agents have also been in use for an extensive period. Other flavors have been added or eliminated from time to time as new products have been

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introduced or existing products have been reformulated in response to changing consumer preferences.

3. Why are so many ingredients used?

ANSWER: A relatively small number of ingredients, perhaps one-fourth of those on the list submitted to HHS, are added directly to tobacco as discrete substances during cigarette manufacture. Fifteen of those ingredients comprise over 99% of the total amount, by weight, of ingredients used in the industry. Most of the ingredients on the list submitted to HHS are used in extremely small quantities as part of flavor formulations purchased by the cigarette manufacturers. These formulations often include a relatively large number of ingredients, but typical industry-wide usage of most of these flavor components is under 10 pounds a year. The flavor formulations used by the companies change occasionally as new products are introduced or existing products are reformulated in response to consumer preferences.

4. Are ingredients used in large amounts?

ANSWER: Ingredients do not comprise a significant portion of the final cigarette. Certain ingredients which serve as processing aids are used in volume during the early stages of manufacturing but generally disappear

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in the manufacturing process. The residual amounts of these materials in the final product will be small and often undetectable. A small number of casing materials, moisturizers, and major flavors account for the great bulk of ingredients actually in cigarettes.

A larger number of the ingredients are used as flavors, but these substances are in the final cigarette in minuscule amounts. Most of the ingredients are constituents of proprietary flavor mixtures purchased from flavor suppliers, and usage of each of these ingredients by the entire industry is generally under 10 pounds per year. These ingredients will normally constitute less than one tenth of 1 percent by weight of the final product.

5. Haven't the cigarette manufacturers started using more and more ingredients to compensate for the reduction of tar and nicotine in cigarettes?

ANSWER: Most of the major ingredients used today have been used in cigarette manufacture for decades. It is true that, in recent years, a larger number of flavoring agents have been used -- in part because of an increased number of new brands and changes in existing brands. However, these flavoring ingredients are generally used in extremely small amounts and, in totality, represent less than one tenth of 1 percent by weight of the final cigarette.

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6. Why hasn't the identity of ingredients been provided to the public before?

ANSWER: It is common for companies in highly competitive industries to guard specific product formulas. The flavoring agents added to foods and the fragrances included in cosmetics, for example, are treated as trade secrets and need not be disclosed on the labels of these products.

Because they contribute to the taste and appeal of individual brands, the identities of specific ingredients in cigarettes are also closely guarded trade secrets. Disclosure of the ingredients used in cigarette manufacture could reveal product formulas that required years of research to develop. The Federal Cigarette Labeling and Advertising Act recognizes the highly confidential nature of ingredients information by directing HHS to establish procedures to protect the confidentiality of the ingredients list.

Even though the ingredients are trade secrets, it should be noted that prior to the passage of Section 7(a) of the Federal Cigarette Labeling and Advertising Act in 1984, the industry had voluntarily cooperated with HHS on the question of ingredients. Under an agreement reached in 1982, the manufacturers had provided HHS with a list of commonly-used ingredients added to tobacco in the manufacture of cigarettes. The industry agreed then to

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consult with HHS as it addressed any questions about specific ingredients.

7. What specific steps will industry take to cooperate with the Department of Health & Human Services in its review of the list?

ANSWER: The industry plans to participate in HHS' scientific review of the list. We are waiting for HHS to complete its initial evaluation of the list before determining what specific steps should be taken.

8. Don't consumers have the right to know what is in the products they buy?

ANSWER: The formulas of any number of consumer products are not treated as public information. These formulas often have great competitive value and require substantial time and expense to develop. The law therefore allows them to be treated as trade secrets. Coca Cola is a well-known example of a product whose formula is secret. The flavorings used in hundreds of other foods and the fragrances used in cosmetics are also treated as trade secrets.

9. Why aren't the ingredients used in cigarettes listed on the package?

ANSWER: As noted above, the identities of specific ingredients used in a particular brand of cigarettes are

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important trade secrets. The specific formula for a brand may take years of time and millions of dollars to develop, and the law recognizes that such valuable information is entitled to confidential treatment.

10. The list of additives which has been supplied to HHS consists of those substances which are currently added to cigarettes. Have any substances been phased out of use in cigarettes since the request for this list was first made?

ANSWER: Like almost all consumer products, from frozen foods to breads or soft drinks, cigarettes undergo constant change as new brands are introduced and old brands are modified or phased out. Most of the modifications in the composition of cigarettes affect flavor constituents used in extremely small quantities. For many of these ingredients, the amount used annually is less than ten pounds for the entire industry. The major ingredients change less often, and many of them have been used for years.

The cigarette manufacturers have complied with the procedures adopted by HHS by submitting an initial list on April 2, 1986. An annual list will be submitted starting December 31, 1986. Any future changes in the ingredients used in cigarettes will be reflected in the lists submitted annually.

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11. Are there any substances currently added to cigarettes sold only in other markets, particularly Third World markets, which are not used in cigarettes sold in the United States?

ANSWER: The Federal Cigarette Labeling and Advertising Act only requires that information be submitted concerning ingredients used in cigarettes sold in the United States, and we have not compiled information on cigarettes sold in other countries.

12. Are ingredients added to filters, and if so, what ingredients are added and what tests have been done to evaluate their safety?

ANSWER: The Federal Cigarette Labeling and Advertising Act only requires that information be submitted concerning ingredients added to the tobacco used in cigarettes sold in the United States. We have not compiled information on ingredients which might be added to other portions of the cigarette.

13. Are the ingredients used safe?

ANSWER: The industry does not believe that the addition to cigarettes of the ingredients on the list is harmful to smokers.

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[Note -- product liability counsel believe this and other questions concerning safety should not be responded to directly.]

14. What evidence is there that the ingredients are safe?

ANSWER: Most of the ingredients are approved for use in foods by the Food and Drug Administration and are included in other lists of approved food, drug, and cosmetic ingredients in the United States and other countries. The inclusion of ingredients on these lists generally reflects a careful review of available data by government and independent scientists. Many of the ingredients are also included on approved lists of tobacco additives in Great Britain and Germany. These lists were prepared by government and independent scientists familiar with the uses of ingredients and information on their safety.

The companies have likewise reviewed available scientific evidence about the ingredients on the list. This includes test data found in the published scientific literature, as well as the results of unpublished research, on many of the ingredients. The safety of the ingredients for use in foods and other articles for human consumption is supported by the available data. The data also indicate that the presence of ingredients in

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cigarettes does not materially affect the chemical composition of cigarette smoke.

15. Are there any substances which have historically been used as additives in cigarettes which are now regarded as hazardous?

ANSWER: In the past, the cigarette manufacturers have reviewed the questions that have arisen concerning ingredients. The industry does not believe that the addition to cigarettes of ingredients formerly or currently used has been harmful to smokers.

16. Why is there any reason to think that an ingredient is safe just because it has been used for a long period of time?

ANSWER: Longstanding use does not alone establish an ingredient's safety. However, most of the major ingredients used in large quantities in the production of cigarettes are either foods or are approved for use in foods or in the manufacture of food products. For these ingredients test data are available concerning both their food and tobacco applications. Despite extensive use, no evidence has been presented to establish that the addition of these ingredients to cigarettes is harmful to smokers.

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17. What effect do ingredients have on non-smokers exposed to cigarette smoke?

ANSWER: As stated earlier, the industry does not believe that the addition to cigarettes of the ingredients on the list is harmful to smokers. We likewise do not believe that the addition of ingredients to cigarettes is harmful to non-smokers who may be exposed to cigarette smoke.

18. Have each of the ingredients been tested to ensure that they are safe?

ANSWER: Since most of the ingredients are approved for use in foods, testing to determine their toxicity has been conducted, and the results have been made available to FDA. The tobacco companies have conducted additional testing on many ingredients which attempts to address the conditions encountered during cigarette smoking. Testing programs by cigarette manufacturers have focused on those ingredients used in the largest quantities and selected components of flavor mixtures. It has been impractical to test each of the many flavor components used in trace quantities.

19. What kinds of tests have been done on ingredients?

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ANSWER: The need for testing, and the types of tests to be conducted, depend on a range of factors. There is no accepted testing methodology for evaluating ingredients and the relevance of the different tests which have been used is uncertain. Nonetheless, depending on the circumstances, the studies conducted include inhalation studies, mouse skin painting studies, and various *in vitro* studies to determine the biological activity of the smoke condensate of cigarettes to which ingredients have been added. In addition, tests have been done to determine whether the presence of ingredients in cigarettes affects the chemical composition of tobacco smoke.

20. The GRAS list and others list many of these ingredients as fit for human consumption, but fail to address the issue of potential dangers posed by the burning of these substances. What research has the industry done into the effects of pyrolysis on these substances?

ANSWER: Many of the ingredients are not pyrolyzed in cigarettes. Their boiling points are well below the temperature of a burning cigarette, and instead of burning they are transferred intact into cigarette smoke. Hence, data related to their food uses is useful in evaluating their effects when used in cigarettes.

For many other ingredients, overall usage levels indicate that pyrolysis data is of low priority. Only fifteen or so of the several hundred ingredients account

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for over 99% of the total amount of ingredients used. The rest are used in tiny quantities, generally as part of flavor mixtures purchased from flavor suppliers. Total industry usage of most ingredients is less than ten pounds a year. Moreover, many of the major ingredients are processing aids which appear in the final product in trace amounts, if at all. For ingredients present in cigarettes in minimal quantities, the absence of significant exposure potential limits the need for pyrolysis testing.

Finally, research has shown that the pyrolysis of ingredients added to cigarettes does not significantly modify the composition of tobacco smoke. Tests have been done using research cigarettes containing much larger amounts of added ingredients than are used in commercial cigarettes. The smoke and/or the condensate from these cigarettes have been evaluated through animal and other tests that have been used in scientific research to investigate the biological effects of cigarette smoke. The tests have not demonstrated that the addition to cigarettes of the ingredients on the list is harmful to smokers.

21. Why haven't pyrolysis tests been run for all ingredients being used?

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ANSWER: Many ingredients used in cigarettes are not pyrolized. They have relatively low boiling points, below the temperature of a burning cigarette, and they are transferred intact from the cigarette to the tobacco smoke. In fact, flavoring agents are often selected for their low boiling points, which assure that their flavoring properties are imparted to cigarette smoke. Hence, for these ingredients, pyrolysis tests are not relevant.

Pyrolysis testing on other types of ingredients is unnecessary in view of the manner in which they are used. Processing aids, for example, appear in the final product, if at all, in trace amounts. In addition, a large number of ingredients used as flavor components are likewise found in cigarettes in minuscule quantities.

22. Are there any studies which examine the effects of the ingredients when they have been inhaled?

ANSWER: Such studies have been done on some ingredients. These studies have not shown that the addition to cigarettes of the ingredients tested is harmful to smokers.

23. What value is any test other than a pyrolysis or inhalation test?

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ANSWER: When an ingredient is not pyrolized, data from tests conducted by the inhalation route of exposure can be used directly in evaluating the ingredient. Tests conducted by the oral route are less definitive but can possess value. Scientists who evaluate the risks associated with substances often use tests conducted using one route of exposure to make judgments about other exposure conditions.

24. Are you aware of any adverse health data generated either by the companies or available in the published literature?

ANSWER: Based on its review of available data and information, the industry does not believe that the addition of the ingredients to cigarettes is harmful to smokers.

25. Is more testing of ingredients planned?

ANSWER: The testing of ingredients has been conducted by individual companies on their own initiative. Companies will continue to conduct tests where they believe such tests are warranted.

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26. You have noted that various bodies such as FEMA or FDA have approved the ingredients for use in foods. Why does that matter, since those organizations have not burned the ingredients?

ANSWER: The inclusion of the ingredients on lists of substances approved for food use by FEMA or FDA indicates that data have been reviewed by independent scientists, who have concluded that the ingredient is suitable for human consumption. It may be appropriate to consider other types of data as well, but FDA's and FEMA's approval of the ingredients should receive considerable weight in evaluating exposure to the same substances through other routes.

27. Isn't it true that the committees which compiled the list of approved tobacco additives in Great Britain and in Germany did not have much information available to them about specific ingredients, but rather conducted a cursory examination?

ANSWER: These committees included independent scientists and government representatives. In developing a list of approved substances, they examined the evidence they believed necessary to make an adequate safety evaluation, and concluded that the ingredients were suitable for use in cigarette manufacture. In some cases, the committees had available to them a large body of evidence, including test results. In other instances, a smaller amount of evidence may have been available,

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particularly for substances typically used in only small quantities. Nevertheless, we believe the review was independent and thorough.

28. What are the large-volume ingredients, why are they used, and what is known about their safety?

ANSWER: While comment on the identity of the major ingredients would be inappropriate, they generally have been used in cigarettes for decades and are extensively used in foods. Most of these ingredients serve as casing materials, humectants, or processing aids. As explained earlier, processing aids will remain in the final cigarettes only in trace amounts, if at all. Casing materials assist in producing a cigarette with a satisfactory taste and texture, and humectants serve to retain the moisture in cigarettes. Certain ingredients used as flavors in the more popular brands of cigarettes may also be used in larger quantities.

A variety of tests have been done to evaluate the safety of the major ingredients. These include tests by the companies, as well as other work reflected in the published literature. Based on the available information, the industry does not believe that the addition to cigarettes of the ingredients on the list is harmful to smokers.

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29. How many known carcinogens are on the list of ingredients which was submitted to HHS?

ANSWER: None of the substances on the list are considered potential human carcinogens by the National Toxicology Program (NTP) or other expert organizations responsible for evaluating the carcinogenic potential of substances.

30. Have the cigarette manufacturers ever used cloves, eugenol, or coumarin in their cigarettes?

ANSWER: Because specific ingredients are important trade secrets, the industry will not comment on whether these substances are being or have been used.

[Note -- this response will be used for all questions about specific ingredients.]

31. The list that has been released contains ingredients such as cloves, eugenol and coumarin. Is the industry really using these compounds?

ANSWER: The list which has been publicly released was prepared by HHS from submissions it received not only from Covington and Burling on behalf of the six major manufacturers, but from other manufacturers and importers of cigarettes as well. We can state categorically that none of the specified ingredients were contained on the

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list submitted on behalf of the six major American tobacco companies.

32. A government scientist referred in a recent article in Mother Jones magazine to an unidentifiable "Compound X" which he had discovered in a cigarette. Does this compound really exist, and if so, what does the industry know about it?

ANSWER: The companies have no information about the specific compound which is referred to but not identified in the Mother Jones article.

33. Why is the industry using Covington and Burling as its spokesperson?

ANSWER: The Federal Cigarette Labeling and Advertising Act allows companies jointly to designate an agent to prepare a combined list of ingredients. Covington and Burling assisted the industry in earlier discussions with HHS concerning ingredients, and the companies asked Covington and Burling to continue that representation in preparing the required list.

34. Isn't it true that you really do not know what effect these ingredients are having on the health of smokers?

ANSWER: The companies have reviewed the scientific literature on ingredients and, where appropriate, they have conducted their own tests to obtain additional

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scientific evidence. The industry does not believe that the addition to cigarettes of the ingredients on the list is harmful to smokers.

35. Don't ingredients simply add to the danger presented by cigarettes?

ANSWER: The industry does not believe that cigarettes have been shown to be dangerous through appropriate scientific tests, or that the addition to cigarettes of the ingredients is harmful to smokers.

36. In the light of the nonchalant way in which the cigarette industry has used untested additives in billions of cigarettes every year, isn't it time that ingredients were brought under the aegis of the FDA?

Answer: HHS will evaluate the list of ingredients submitted by the industry and is charged by Congress with preparing a report on ingredients. We see no reason to create an additional review mechanism.

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